510(k) Summary of Safety and Effectiveness K120773

Submitter

Covidien LLC
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JUL 10 2012

Company Contact: Mia M. Ware, Sr. Regulatory Affairs Specialist

Date Summary Prepared: January 10, 2012

Device Name

Trade Name:	Nellcor™ Bedside SpO_2 Patient Monitoring System
Common Name:	Oximeter
Classification Name:	Oximeter (21 CFR 870.2700)
Classification:	Class II
Product Code:	DQA

Predicate Devices (Legally Marketed Devices)

The predicate device for the Nellcor™ Bedside SpO_2 Patient Monitoring System is:

- **Covidien** Oximeter, Model Nellcor OxiMax N-600x Pulse Oximeter with SPD cleared by FDA through 510(k) No. **K083325**

Device Description

The Nellcor™ Bedside SpO_2 Patient Monitoring System provides continuous, noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate.

Intended Use

The Nellcor™ Bedside SpO_2 Patient Monitoring System is indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. The Nellcor™ Bedside SpO_2 Patient Monitoring System is intended for prescription use only with neonatal, pediatric, and adult patients, and for patients who are well or poorly perfused, in hospitals, hospital-type facilities, and intra-hospital transport.

Note:

- Hospital use typically covers such areas as general care floors (GCFs), operating rooms, special procedure areas, intensive and critical care areas within the hospital, and in hospital-type facilities.
- Hospital-type facilities include physician office-based facilities, sleep labs, skilled nursing facilities, surgicenters, and sub-acute centers.
- Intra-hospital transport includes transport of a patient within the hospital or hospital- type facility.

Summary of Technical Characteristics of the Device Compared to the Predicate Devices (Legally Marketed Devices)

The Nellcor Bedside SpO_2 Patient Monitoring System is substantially equivalent to the Covidien, Nellcor OxiMax N-600x Pulse Oximeter with SPD.

The clinical performance of the Nellcor Bedside SpO_2 Patient Monitoring System when used with adult, pediatric and neonatal patients is equivalent to the Nellcor Puritan

Bennett, model OxiMax N-600X Pulse Oximeter with. The Nellcor™ Bedside SpO_2 Patient Monitoring System consists of the NELL1SR PCBA (oximetry board) for its performance of Pulse Oximetry and uses the same Oximax SpO_2 technology and software algorithm as the predicate device, N-600X. It is intended to be used with the same Nellcor SpO_2 sensors that are commercially available and used with the predicate device. Because there are no changes to the performance, technology, and intended use of the device, the clinical data submitted as part of the premarket notifications for the predicate device (N-600X) also applies to the Nellcor Bedside SpO_2 Patient Monitoring System.
The pulse rate derived from the pulse oximetry (SpO_2) channel of the Covidien LLC. model Nellcor Bedside SpO_2 Patient Monitoring System has the extended measurement range of 20 to 250BPM, same as the Nellcor model OxiMax N-600X Pulse Oximeter with SPD.

Summary of Performance Testing

The Nellcor Bedside SpO_2 Patient Monitoring System has been tested in accordance with the system V & V summary (#MDR-YW110610-01) included with the submission using production equivalent units prior to release to market. A summary matrix of the V&V testing is included in section 17 of this submission.

A risk analysis identifying potential hazards and documenting mitigation of the hazards has been developed and applied as part of Mediana design control procedure. Mediana's quality system confirms to 21CFR820, ISO 9001, ISO13485 and CMDCAS ISO 13485 certified by DNV (Det Norske Veritas) and QMI (Quality Measuring Instrument).

Conclusions

As stated above, the Nellcor Bedside SpO_2 Patient Monitoring System is safe and effective, complies with the appropriate medical device guidance and standards and is substantially equivalent to the predicate device.

-End of Section-

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room --WO66-G609
Silver Spring, MD 20993-0002

Covidien LLC
C/O Mr. Charlie Mack
International Regulatory Consultants
77325 Joyce Way
Echo, Oregon 97826

JUL 10 2012

Re: K120773
Trade/Device Name: Nellcor™ Bedside SpO_2 Patient Monitoring System
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: June 8, 2012
Received: June 14, 2012

Dear Mr. Mack:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: _____

Device Name: Nellcor™ Bedside SpO_2 Patient Monitoring System

Indications for Use:

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Prescription Use__X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schilling

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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